# 외국의 임상진료지침 개작 현황

2009. 9.11

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# Background

- **Developing Clinical Practice Guidelines (CPGs) needs**
  - a formal and rigorous approach
  - resources and expertise
  - time

- **The challenge is keeping guidelines up to date, as resources are limited.**

# Guideline adaptation

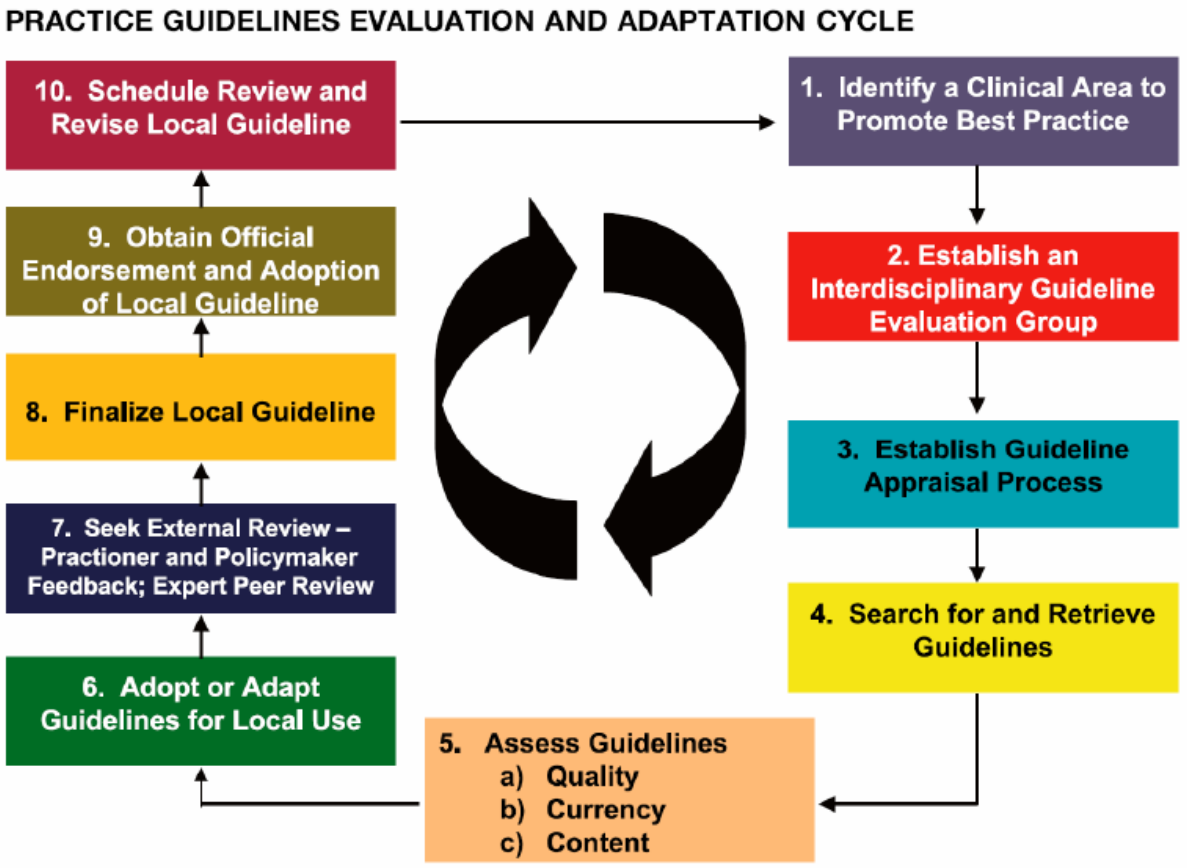
- *Modification of guideline(s) produced in one cultural and organizational setting to be used in a different cultural organizational context.*

  -> Taking advantage of existing guidelines to reduce duplication of effort

# Checklist for identifying guidelines requiring adaptation : WHO

| Factors influencing the applicability or transferability of guidelines across different settings | Response (positive answers increase the likelihood that recommendations should be flagged as requiring adaptation) |
|---|---|
| 1. Is there important variation in need (prevalence, baseline risk or health status) that might lead to different decisions? | ☐ Yes<br>☐ Unclear<br>☐ No |
| 2. Is there important variation in the availability of resources that might lead to different decisions? | ☐ Yes<br>☐ Unclear<br>☐ No |
| 3. Is there important variation in costs (e.g. of drugs or human resources) that might lead to different decisions? | ☐ Yes<br>☐ Unclear<br>☐ No |
| 4. Is there important variation in the presence of factors that could modify the expected effects (e.g. resistance patterns of microbiological pathogens), which might lead to different decisions? | ☐ Yes<br>☐ Unclear<br>☐ No |
| 5. Is there important variation in the relative values of the main benefits and downsides that might lead to different decisions? | ☐ Yes<br>☐ Unclear<br>☐ No |

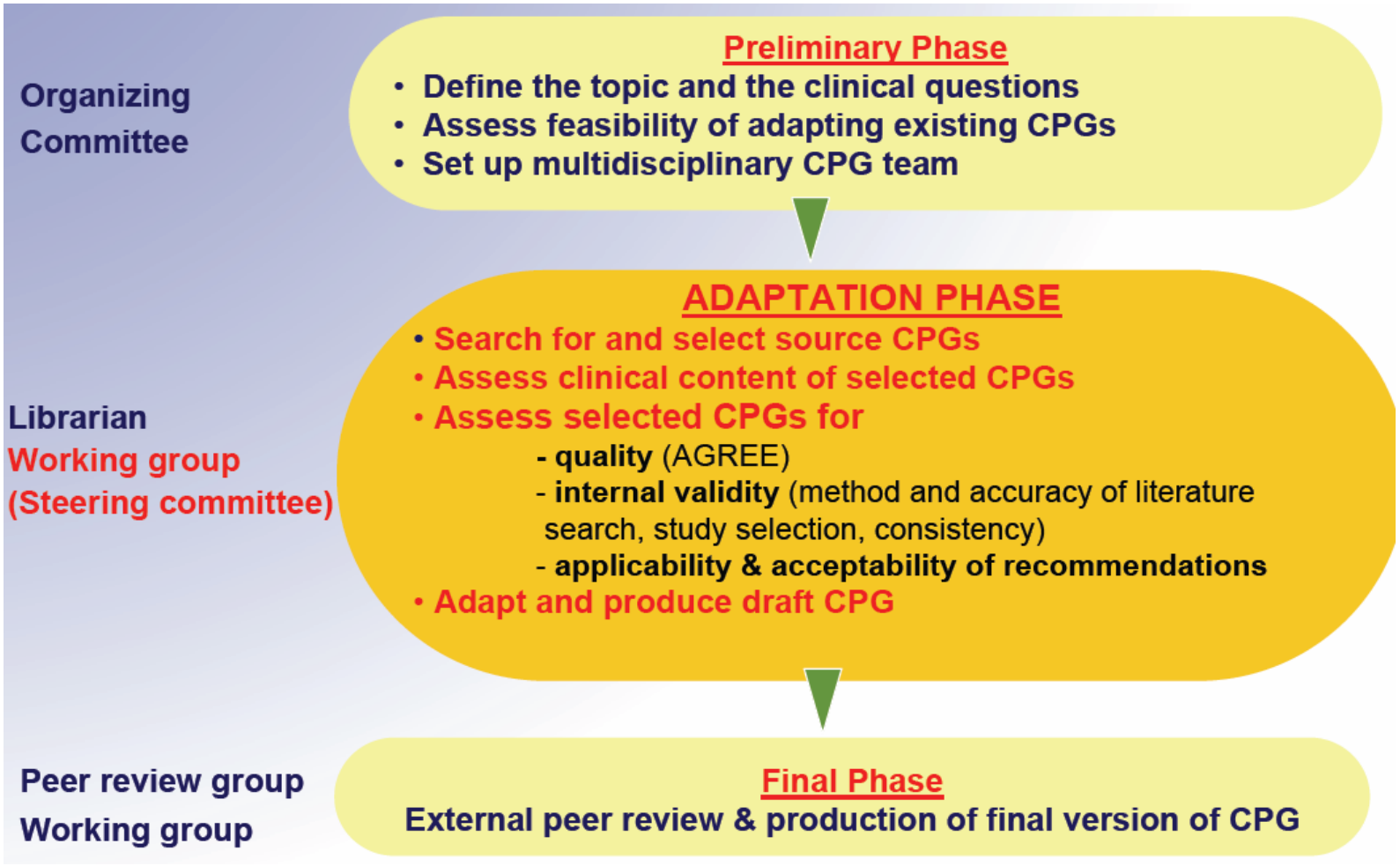
# How should recommendations be adapted? : WHO



## Haute Autorité en santé (HAS)

- **Active management of labour (>37 weeks pregnant)**
- **Recommendations**
  - Same recommendation in source-CPG and French-CPG :3
  - No recommendation (summary or not addressed) in source-CPG but recommendation in French-CPG :11
  - More precise recommendation in French-CPG :2
  - Recommendation adapted to the local context :6
- **Grading**
  - No change of grading in recommendations from source-CPGs
  - Grading of 11 recommendations

# HAS' Adaptation Process

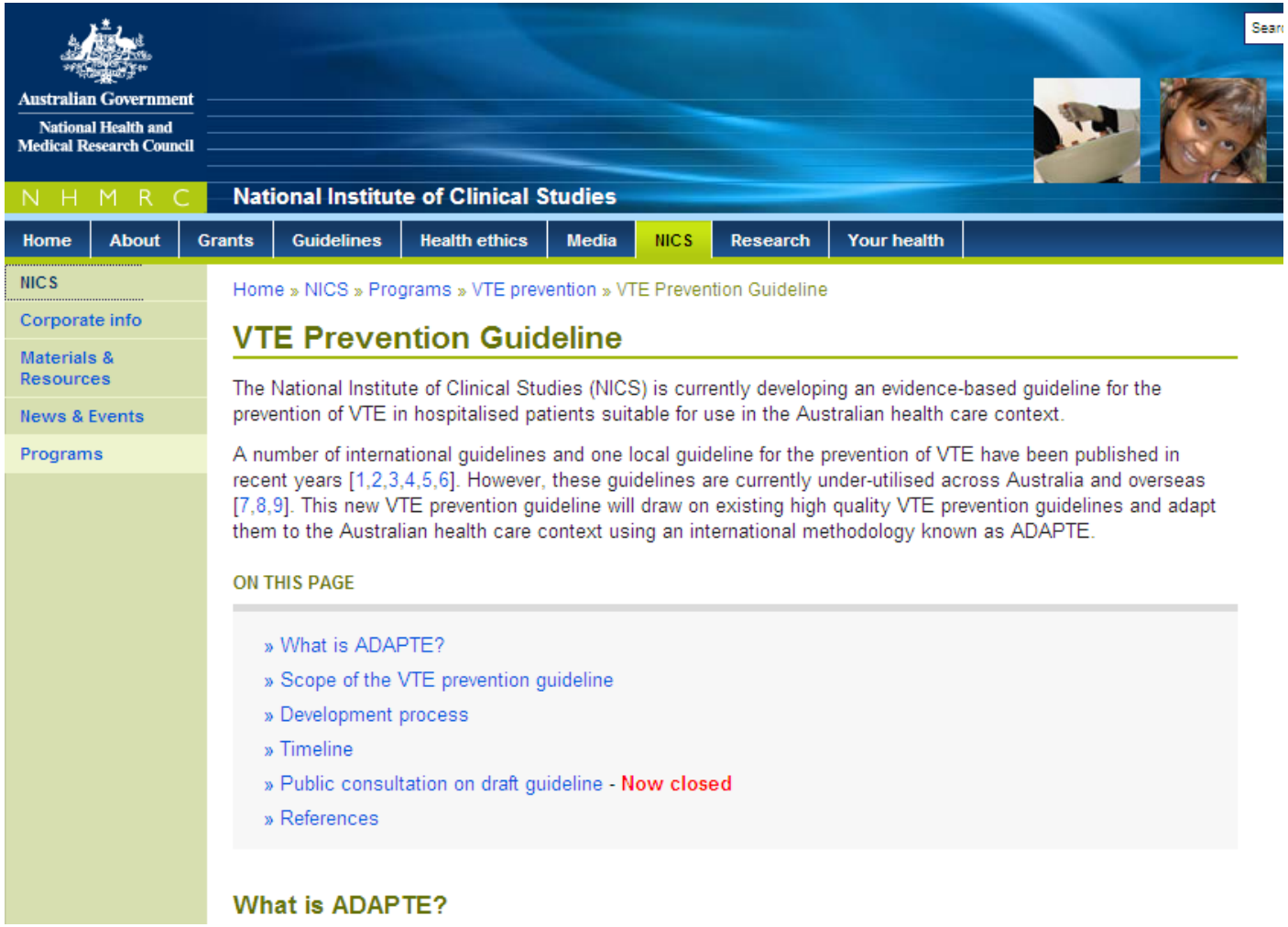


# Working group's opinion in HAS

- **Little enthusiasm at first**
  - Time needed
  - Fear of  having insufficient expertise
- **Very happy after experiencing the method**
  - Better understanding of CPG development
  - More proficient in critical reviewing
- **Can one trust someone else's work ? !**
  - Explicit evidence tables are needed
- **Does adaptation shorten the development process and reduce resources?**
  - Less time searching for and acquiring documentation
  - Workload reduced
  - However, HAS' recruitment and administrative procedures lengthy
- **The quality and implementability of the derived CPG has to be assessed!**

# NHMRC, National Institute of Clinical Studies(NICS)

NCRC KGC



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Home » NICS » Programs » VTE prevention » VTE Prevention Guideline

## VTE Prevention Guideline

The National Institute of Clinical Studies (NICS) is currently developing an evidence-based guideline for the prevention of VTE in hospitalised patients suitable for use in the Australian health care context.

A number of international guidelines and one local guideline for the prevention of VTE have been published in recent years [1,2,3,4,5,6]. However, these guidelines are currently under-utilised across Australia and overseas [7,8,9]. This new VTE prevention guideline will draw on existing high quality VTE prevention guidelines and adapt them to the Australian health care context using an international methodology known as ADAPTE.

ON THIS PAGE



### What is ADAPTE?

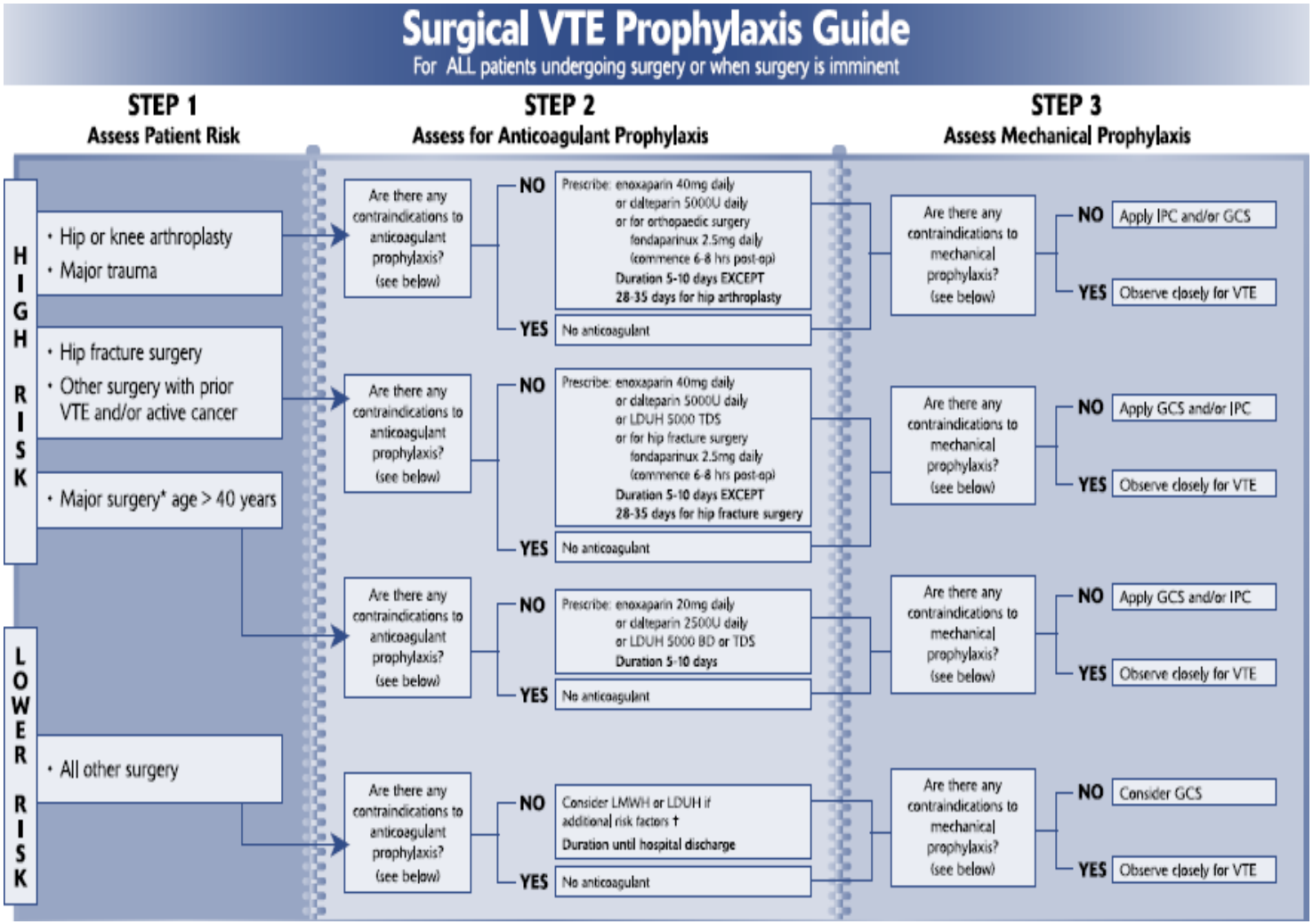
# VTE Prevention Guideline

- The development of this guideline is being undertaken by the National Health and Medical Research Council's National Institute of Clinical Studies.

- This work is supported by the VTE Prevention Guideline Adaptation Committee.

These updated guidelines have been developed by the Australia and New Zealand Working Party to assist in the identification and treatment of patients at risk of developing venous thromboembolism (VTE). The recommendations are based on the International Union of Angiology (IUA) and American College of Chest Physicians (ACCP) consensus statements adapted to Australia and New Zealand conditions. The recommendations issue from evidence based practice using the highest level of evidence available.

There are many clinical situations where the literature provides little information to direct recommendations for VTE prophylaxis. In these circumstances, the Australia and New Zealand Working Party has applied recommendations based on expert judgement and experience. These recommendations are the combined views of surgeons and physicians expert in thrombosis management and reflect their interpretation of available evidence as well as their subjective opinions about the relative effectiveness, hazard and cost of alternatives.


Surgical VTE Prophylaxis Guide
For ALL patients undergoing surgery or when surgery is imminent
STEP 1
Assess Patient Risk
STEP 2
Assess for Anticoagulant Prophylaxis
STEP 3
Assess Mechanical Prophylaxis
HIGH RISK
• Hip or knee arthroplasty
• Major trauma
• Hip fracture surgery
• Other surgery with prior VTE and/or active cancer
• Major surgery* age > 40 years
LOWER RISK
• All other surgery
Are there any contraindications to anticoagulant prophylaxis? (see below)
NO
YES
Prescribe: enoxaparin 40mg daily
or dalteparin 5000U daily
or for orthopaedic surgery
fondaparinux 2.5mg daily
(commence 6-8 hrs post-op)
Duration 5-10 days EXCEPT
28-35 days for hip arthroplasty
No anticoagulant
Are there any contraindications to mechanical prophylaxis? (see below)
NO
Apply IPC and/or GCS
YES
Observe closely for VTE
Are there any contraindications to anticoagulant prophylaxis? (see below)
NO
YES
Prescribe: enoxaparin 40mg daily
or dalteparin 5000U daily
or LDUH 5000 TDS
or for hip fracture surgery
fondaparinux 2.5mg daily
(commence 6-8 hrs post-op)
Duration 5-10 days EXCEPT
28-35 days for hip fracture surgery
No anticoagulant
Are there any contraindications to mechanical prophylaxis? (see below)
NO
Apply GCS and/or IPC
YES
Observe closely for VTE
Are there any contraindications to anticoagulant prophylaxis? (see below)
NO
YES
Prescribe: enoxaparin 20mg daily
or dalteparin 2500U daily
or LDUH 5000 BD or TDS
Duration 5-10 days
No anticoagulant
Are there any contraindications to mechanical prophylaxis? (see below)
NO
Apply GCS and/or IPC
YES
Observe closely for VTE
Are there any contraindications to anticoagulant prophylaxis? (see below)
NO
YES
Consider LMWH or LDUH if additional risk factors †
Duration until hospital discharge
No anticoagulant
Are there any contraindications to mechanical prophylaxis? (see below)
NO
Consider GCS
YES
Observe closely for VTE

# Swiss : Adapting guidelines for the management of headache in an emergency care centre

- **Rationale for developing guidelines for headache management**
  - Frequent complaint
    - Large variations in management
    - Diagnostic approach
      - Imaging techniques
      - Referral to specialist
  - Need a common framework
  - Patients triage of emergency cases
    - Inpatient/Outpatient
- **Guidelines for the diagnostic evaluation of patients presenting in emergency for an acute non-traumatic headache (Rev Med Suisse. 2008 Aug 20;4(167):1741-6)**

# Context

- Limited resources
- One institution (Academic Medical Centre)
- Management of headache limited to initial, diagnostic work-up, not to treatment
- Intend to adapte and not develop guidelines

# Adaptation steps followed-Difficulties

- **Most ADAPTE steps followed**
- **Simplified, pragmatic approach**
  - Initial meeting: e-mail (key documents / guidelines)
    - Reducing number of guidelines (date and theme)
    - Difficulty when question of interest is only present in low quality guideline
  - Checking guideline consistency
  - Only rarely went back to original studies
  - Unsure if we can / will get back to source guidelines authors

# Adaptation steps followed-Difficulties

- **Development of a list of recommendations based on existing guidelines**
- **Two round adapted Delphi process used with a multidisciplinary panel**
- **Difficulties**
  - Too many options for diagnostic imaging
  - Overlapping, but dissimilar, multiple recommendations
  - A second round of recommendations was necessary
  - Most often based on expert opinion

# CANADA : Guideline Adaptation Project

NCRC KGC

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## Strategic Initiative: Guideline Adaptation Project

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**Evidence-based principles, knowledge-to-action key elements**

**March 11, 2009** — Through the Guideline Adaptation Project, the Partnership's Cancer Guidelines Action Group is making it possible to extend the reach of existing cancer control guidelines.

The project is developing and evaluating a methodology to facilitate the work of groups who are adapting existing guidelines. Building on existing guidelines may improve the quality and efficiency of the guideline development process and reduce the duplication of effort.

Importantly adaptation promotes the planning process for implementing a guideline as groups consider the 'fit' with recommendations, local barriers and facilitators.

# Guideline Adaptation Group (CAN-ADAPTE)

- **ADAPTE Collaboration and 6 Canadian GDGs**
- **Evaluation of the international ADAPTE methodology:**
  - The six case study groups using the 24-step process of the ADAPTE Manual and Resource Toolkit and evaluating what works in a Canadian context.
- **Development of a CAN-ADAPTE toolkit:**
  - Drawing on the experiences of the case study groups, the toolkit will provide future guideline developers with a reliable methodology for adapting existing guidelines for their region—pan-Canadian, provincial, regional or local.
- **Implementation of knowledge-to-action:**
  - Review of an existing guideline also gives guideline developers the opportunity to consider how it may be adapted to their setting and, just as important, how it can be put into action as quickly and easily as possible.
  - By addressing potential barriers and considering prospects for facilitating action before the guideline is completed, cancer centres, policy-makers and administrators can better plan for implementation of the guideline.

# Utilizing the ADAPTE Tools for Metastatic Breast Cancer Guideline

- **Decisions were**
  - To ADAPTE recommendations for some questions
  - Develop de-Novo recommendations for others

- **De-novo recommendations to be based on the last 2-3 years evidence and meta-analysis done for survival and response rates.**

# Set-Up Phase –Preparation Module

- **Panel included (7) ;**
  - 4 oncologist, Nurse, Pharmacist , Methodologist

- **Helpful Tools**
  - Tool 1:Guideline adaptation and implementation
  - Tool 2:Search sources and strategies
  - Tool 3:declaration of conflict of interest signed by all
  - Tool 5:Work-plan included in the protocol
  - Tool 4:Consensus process resources Not used

# Adaptation Phase
# - Scope and Purpose

- **Helpful Tools : Tool 6**
  - P: patient population (MBC)
  - I: Interventions (Taxanes)
  - P: Professionals targeted (practitioners)
  - O: expected outcomes (survival/response)
  - H: Health care setting and context (Tertiary care setting )

# Optimal Use Of Taxanes In Metastatic Breast Cancer : Clinical Questions

- What taxane regimens can be offered to anthracycline-naïve patients with metastatic breast cancer where HER2 is not over-expressed?
- What taxane regimens can be offered to anthracycline-pretreated/resistant patients with metastatic breast cancer where HER2 is not over-expressed?
- What taxane regimens can be offered to patients with metastatic breast cancer where HER2 is over-expressed?
- What are the benefits (time to progression, progression free survival, overall survival, quality of life)?
- What are the potential toxicities?

# Adaptation Phase –Search and Screen

- **Helpful Tools**
  - Tool 2:Search sources and strategies
  - Tool 7:table for summarizing guidelines
  - Tool 8:table for recording clinical content of CPG
  - Tool 9:AGREE
  - Tool 10:AGREE inter rater agreement spread sheet not available

# Adaptation Phase –Search and Screen

- **Literature Search Strategy**
  - **Guidelines and other evidence :**
    - medline, PubMed, cinahl, embase, CancerLit, Cochrane Library, the Physician Data Query database, practice guideline internet sites, and conference proceedings from the American Society of Clinical Oncology (asco) and the San Antonio Breast Cancer Symposium
  - **Search terms :**
    - Taxane* Exp., Taxanes Exp., metastatic breast cancer exp., metastases, breast tumor, Women exp., adding AND/OR Anthracycline exp., Anthracyclines exp.

# Adaptation Phase –Search and Screen

- **Search period :**
  - **January 1, 2000, to August 31, 2007.**
  - **Given that the most up-to-date evidence-based guideline selected was published in 2003,**
  - **Other evidence was conducted for the period January 1, 2003, to January 1, 2007.**
    - Other evidence cited in bibliographies and brought forward during editing and review was collected as necessary.

# Objectives of Guidelines selected

- **Six Guidelines were found and two selected**

- Alberta Cancer Board (ACB)
  - To determine the optimal use of taxanes in the management of metastatic breast cancer.
- **Cancer Care Ontario (CCO)**
  - What is the role of the taxanes in the management of metastatic breast cancer?
- **National Institute for Health & Clinical Excellence (NICE)**
  - Guidance on the use of taxanes for the treatment of breast cancer.

# Adaptation Phase –Assessment Module Decision and Selection Module and Customization Module

- Tool 12: recommendation matrix
- Tool 13:search and selection evaluation sheet

# Agree Instrument Analysis for CCO and NICE score

| Domain | Guideline | Obtained score | Standardized[11] score % | Mean and SD |
|---|---|---|---|---|
| Scope and Purpose | CCO | 69 | 94.44% | 3.83 ± .28 |
| | NICE | 60 | 77.78% | 2.67 ± .76 |
| Stakeholders involvement | CCO | 66 | 58.33% | 2.75 ± .32 |
| | NICE | 55 | 43.06% | 2.29 ± .81 |
| Methodology (items 8-14) | CCO | 149 | 84.92% | 3.50 ± .39 |
| | NICE | 143 | 80.16% | 3.40 ± .78 |
| Clarity and presentation | CCO | 89 | 90.27% | 3.70 ± .29 |
| | NICE | 83 | 81.94% | 3.45 ± .78 |
| Applicability | CCO | 36 | 33.33% | 2.00 ± .84 |
| | NICE | 48 | 55.56% | 2.67 ± .92 |
| Methodology (item 22-23) | CCO | 34 | 61.11% | 2.83 ± 1.03 |
| | NICE | 36 | 66.67% | 3.00 ± .78 |
| Overall assessment | CCO | 20 | ---- | 3.33 ± .51 |
| | NICE | 18 | ---- | 3.00 ± .63 |

# Agree Instrument Analysis for CCO and NICE

| All Items on the instrument were used | CCO Interrater reliability 0.809 | | NICE Interrater reliability 0.645 | |
|---|---|---|---|---|
| N=24 Items | Mean | Std. Deviation | Mean | Std. Deviation |
| S_physician | 3.13 | 1.08 | 3.04 | 1.04 |
| K-physician | 3.50 | .78 | 3.25 | 0.74 |
| M-Physician | 3.17 | 1.17 | 3.42 | 1.06 |
| Sa-physician | 3.38 | .82 | 3.71 | 0.46 |
| S-pharmacist | 2.83 | 1.20 | 2.67 | 1.05 |
| D-Nurse | 3.25 | 1.15 | 2.33 | 1.37 |

- **Inter rater Agreements :**
- **AGREE tool : CC0 K=0.23/ NICE K=0.11**
- **ADAPTE tool 13 : CC0 K=0.47 /NICE K=0.09**

TABLE I External review questionnaire

| *Question* | *Response frequency* | | |
|---|---|---|---|
| | *Neutral* | *Agree* | *Strongly agree* |
| The guideline panel is credible. | | 1 | 4 |
| The guideline is unlikely to be influenced by vested interests. | | 2 | 3 |
| Rationale for developing the guideline is clear. | | 2 | 3 |
| There is a need for a provincial guideline on this topic. | | 2 | 3 |
| The literature search is relevant and complete. | | 1 | 4 |
| I agree with the methodology used for summarizing the evidence. | | 1 | 4 |
| The results are interpreted according to my understanding of data. | | 2 | 3 |
| The draft recommendations are clear. | | 1 | 4 |
| The draft recommendations are reasonable. | | 2 | 3 |
| When applied, the recommendations will produce more benefit than harm for patients. | | 1 | 4 |
| The recommendations are suitable for the intended patients. | | 2 | 3 |
| The draft report presents options that will be acceptable to patients. | | 1 | 4 |
| When applied, the recommendations would result in better use of resources than current usual practice. | 1 | 2 | 2 |
| Following the recommendations would not require reorganization of services in my practice setting. | | 2 | 3 |
| The draft recommendations are likely to be supported by most of my colleagues. | | 3 | 2 |
| The draft report should be approved as practice guideline. | | 3 | 2 |

# Final Phase –Scheduled Review & Update and Final Production

- Final guideline document will be written by the Chair and edited by Co-chair
- The panel will review and edit
- Methodologist will reformat to for web-posting

# Evaluation of the ADAPTE Process

- **The Second Perception form was administered after the first panel meeting, and the Final Evaluation form just after the Draft Report was sent for external review.**
  - Adherence to the ADAPTE process assessed.
  - The uptake of the ADAPTE steps and tools
  - Extent to which recommendations from source guidelines were adapted.
  - Recommendations were classified as being adopted without modification, adapted (modifications made) and created de novo.

# Recommendations adapted from source guidelines

- The Draft Report contains six recommendations.
- Three recommendations were adapted from the CCO guideline only. Modifications were made to reflect recent evidence.
- One recommendation was adapted from both the CCO and NICE guidelines. Modifications were made to reflect recent evidence.
- Two recommendations were created de novo.
- One of these recommendations was addressed in a separate CCO guideline but still required updating based on recent evidence.
- The other recommendation pertains to a taxane (nab-paclitaxel) for which randomized phase II or III data was unavailable when the CCO and NICE guidelines were developed. An advice report addressing the use of nab-paclitaxel in metastatic breast cancer was posted by the CCO during the writing of our Draft Report.

# Adherence to the ADAPTE process

- **ADAPTE steps not utilized**
  - Currency assessment
  - Consistency assessment
  - Acceptability /applicability assessment
  - Consult with endorsement bodies
  - Consult with guideline developers
- **Reasons**
  - Tool 11 inherent in lit. search
  - Tool 14 : beyond scope of adaptation
  - Tool 15:  inherent in adaptation
  - Inherent in external review
  - Could have significantly delayed the process

# The ADAPTE process offers 18 tools
# 17 were available

1. Tool 1. Guideline Development & Implementation Resources
2. Tool 2: Search Sources and Strategies
3. Tool 3: Declaration of Conflict of Interest
4. Tool 5. Work Plan
5. Tool 6: PIPOH
6. Tool 7: Summarizing guideline characteristics
7. Tool 9: AGREE instrument
8. Tool 12: Recommendation matrix
9. Tool 13: Search and selection of evidence
10. Tool 18: External review surveys

# ADAPTE tools not utilized

- Tool 4. Consensus Process Resources
- Tool 8: Summarizing guideline content
- Tool 10: AGREE calculation spreadsheets
- Tool 11: Currency survey of guideline developers
- Tool 14: Scientific validity (consistency, interpretation & recommendations)
- Tool 15: Acceptability/applicability
- Tool 16: Checklist of adapted guideline content
- Tool 17: Reporting results of update process

## Take home message

- ADAPTE process is useful and can significantly reduce time in producing high quality evidence based guidelines
- The ADAPTE tools are user friendly
- Reduces duplication of effort with emphasis on mutual recognition
- Supports and helps in building mutual trust among different organizations internationally
- Promotes evidence based care and may lead to better patient outcomes

# Conclusions

- **Increase of guideline adaptation and usage of ADAPTAE manual and toolkits**
- **Key process**
  - Defining purpose and scope
  - Selection and complete analysis of guidelines
  - Systematic review of current evidence
    - Take advantage of existing guideline and SR
    - Find domestic evidence
  - Consideration of local context
    - Formal consensus

# Conclusions

- **We should develop Korea-ADAPTE manual**
  - Modification of ADAPTE manual & toolkit
  - Search strategy  for Korean literature
  - How do we consider our context ?
    - Contents
    - Process

Thanks for listening !!!